Facility Monitoring System (FMS) Solutions

Particle Monitoring for ISO 21501 Compliant Pharmaceutical Manufacturing

BECKMAN COULTER

Life Sciences
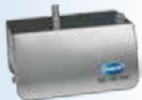
On-line and Portable Particle Counters

With new innovative designs specifically tailored to address the requirements of the Pharmaceutical industry, MET ONE particle counters feature full ISO 21501 compliance in advance of ISO 14644 standard adoption for all calibration parameters. Based on open-architecture communications, they integrate easily with your preferred systems. To make manual monitoring more efficient, MET ONE portable counters feature testing Wizards, automatic and paperless data transfer compliant with 21 CFR Part 11. All our counters support 0.5 μm and 5.0 μm size channels per regulatory requirements.

MET ONE 3400 SERIES

- High Performance: 0.3/0.5 μm sensitivity counter designed for ISO 21501 compliance for data accuracy and repeatability
- Flexible Communications: Ethernet, USB, WiFi and Serial
- Ease of Use: Intuitive wizards reduce workload for classification and compliance
- 21 CFR Part 11 Compliance: Allows secure USB memory stick data transfer
- Configurable for: Portable, on-line or batch use

MET ONE 6000 SERIES

- High Performance: 0.3/0.5 μm sensitivity counter designed for ISO 21501 compliance for data accuracy and repeatability
- Easy to Integrate: Multiple communication options allow easy integration into existing FMS systems
- Long Life Laser Diode: Reduced downtime and reduced cost of ownership
- Built-in Flow Meter: ensure data is valid during validation and monitoring
- Enhanced End User Notification: Added assurance of correct sensor operation, invaluable fault finding tool

MET ONE 6000P SERIES

- All the enhanced features on the 6000 series counters and an integrated pump system
- Microprocessor controlled flow
- Reduced installation cost (no expensive distributed vacuum system required)
- Flexible Installation options (remote areas where vacuum isn't available)

MET ONE 7000 SERIES

- High Performance: 0.3/0.5 μm sensitivity counter designed for ISO 21501 compliance for data accuracy and repeatability
- Protected Sensor: NEMA enclosure with sealed connectors, flow shut-off valve protects counter internals from accidental exposure to harmful disinfecting chemicals
- Enhanced End User Notification: Added assurance of correct sensor operation, invaluable fault finding tool
- Easy to Integrate: Multiple communication options allow easy integration into existing FMS systems
- Long Life Laser Diode: Reduced downtime and reduced cost of ownership
- Built-in Flow Meter: ensure data is valid during validation and monitoring
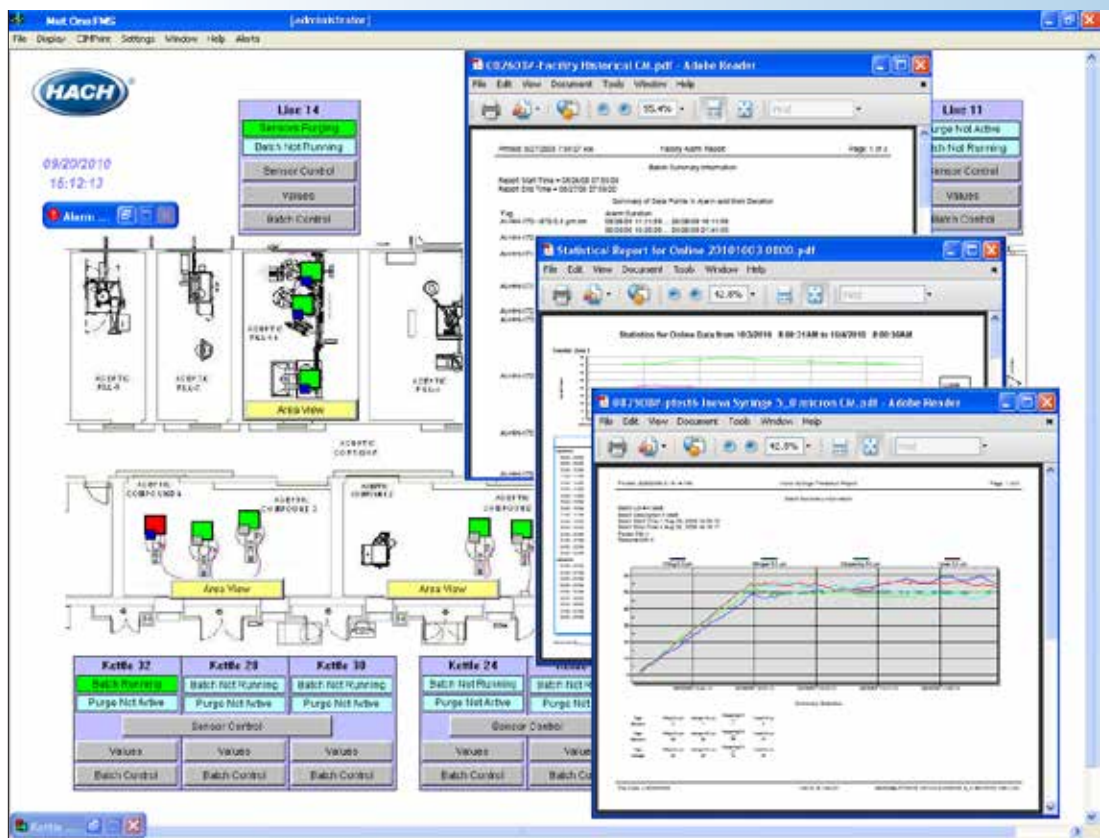
MET ONE MANIFOLD PARTICLE COUNTING SYSTEM

- Sampling Locations: Allows a single 3400 series particle counter to monitor as many as 32 locations
- Continuous Flow: Uses a high-volume pump for continuous flow of air through all ports so particles are not lost due to fallout or surface adhesion

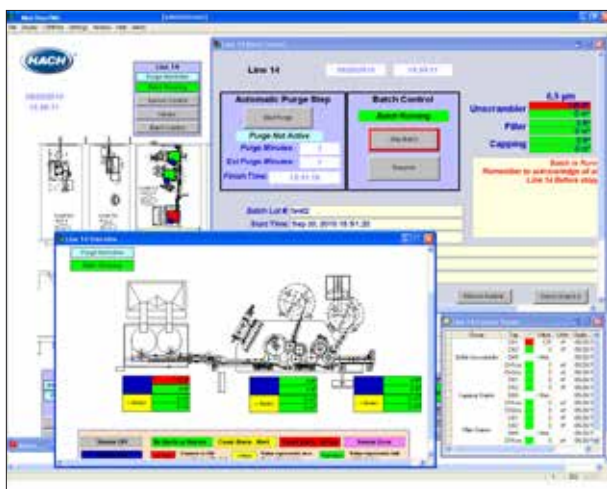## *MET ONE Facility Monitoring System: Paperless - Compliance*

MET ONE FMS solutions set the standard of scalable on-line particle monitoring systems. Whether you run limited, short term aseptic manufacturing or multiple production lines of high-volume filling suites our MET ONE FMS platform adjusts to your specific requirements. Use wireless portables or dedicated on-line sensors, add environmental sensors or mix them all in a batch-driven style of operation. MET ONE FMS manages all data for Grade A sterile areas, including cleanroom classification, pre-production environmental qualification and aseptic on-line manufacturing.
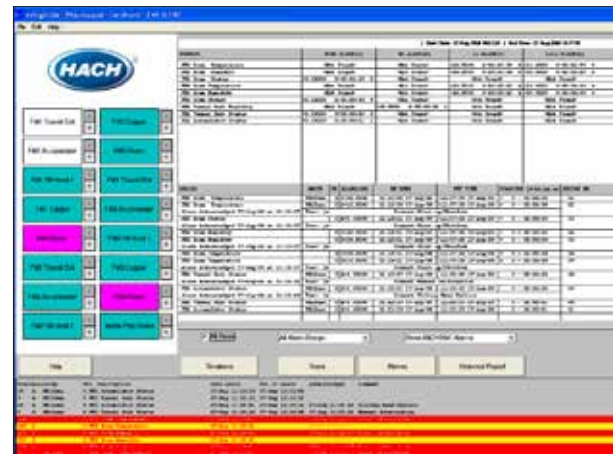
Scalable Software Solutions

MET ONE FMS

- Windows-based SCADA (Supervisory Control and Data Acquisition) software based on the use of a real-time database
- Completely customizable user interface (map of your facility, area or tool)
- Monitor 1 to hundreds of locations simultaneously
- Completely 21 CFR Part 11 compliance (secure data management)
- Integrated secure audit trail
- Single user or client-server system
- Advanced alarming (acknowledgment), reporting, data display (value tables, trend charts)
- Batch-driven data capture, display and reporting
- Industry standard communications protocols (analog, digital, serial, modbus RTU/TCP, OPC)

MET ONE FMS LITE

- Configure a compliant monitoring system in minutes utilizing an easy-to-use wizard
- Monitors up to 20 locations on a single screen
- Provide secure operations using Windows user names and passwords
- Includes system validation documents
- Reporting and data export
- Supports alarm panels
- Supports digital IO and analog environmental sensors (RH/Temp, Delta P)

MET ONE OPC SERVER

- Compatible with all MET ONE air particle counters
- Enables capture of enhanced features beyond just particle counts (flow, calibration dates, location, batch IDs etc.)
- Compatible with most OPC clients
- Enable secure data integration to your ERP, BMS, LIMS or other enterprise network solution

Full Range of Accessories & Service Solutions

COMPLIANCE SERVICES

From assistance with SOP development for manual monitoring, to full validation documentation packages for automated systems, Hach ensures that your particle monitoring program is fully compliant. We assist with URS planning, provide validation documents (IQ/OQ), and guide you through the validation testing process to final sign-off.

SYSTEM DEVELOPMENT SERVICES

When your requirements include automated monitoring, our dedicated Systems Team ensures smooth implementation.

Our service covers each phase of system deployment:

- Project management
- System requirement definition and design
- Software customization
- Validation documentation
- System installation and commissioning

SYSTEM INTEGRATION SERVICES

Our Systems Team are also experts at integrating our instruments with your existing Enterprise Information Systems, LIMS, or Building Management System.

Let us eliminate:

- Data silos and validation for multiple systems
- Multiple reports by including non-viable particle data with all other production data
- Maintenance and upgrades for multiple monitoring systems

ENVIRONMENTAL SENSORS & SYSTEM ACCESSORIES

Hach offers a wide spectrum of accessory items to complete and perfect your facility monitoring system

- Relative humidity and temperature sensors
- Air velocity sensors
- Differential pressure sensors
- IO modules for connecting to existing sensors, door switches, tool interrupts, etc.
- Ethernet switches, touch-screen NEMA computers etc.
- Distributed vacuum systems
- Distributed DC power systems
- Variety of isokinetic sample probe options
- Multi-function alarm modules

Compliance Experts

As the leading provider of particle monitoring systems for Pharmaceutical manufacturing since 1987, MET ONE has the most experience meeting regulatory requirements. Before published regulatory guidance, MET ONE was helping companies meet the recommendations of individual regulators. As new standards and regulations emerged, MET ONE has guided the industry and regulatory community toward practical implementations.

MET ONE provides many services to help you stay abreast of current regulations:

- Regional Life Science User Group seminars
- Compliance Webinars
- On-site consulting and seminars for your particular needs

We can help you design the right particle monitoring program for improved compliance accuracy and productivity.

On-site Service

With industries largest global network of local service offices, we are the only company that can deliver fully compliant on-site service for your instruments, including full ISO 21501-4 calibrations. Each of our automated monitoring solutions report the calibration status of each instrument and proactively notify you of upcoming calibrations to ensure full service compliance of all batch production and environmental monitoring measurements.

Our service agreements program provides proactive pre-scheduled on-site calibration and maintenance services, including discounts for any repairs.

Ask for an on-site survey today!

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